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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,647	03/10/2000	Andrew D. Murdin	032931/0227	5021
7590	05/19/2004		EXAMINER	
Bernhard D Saxe Foley & Lardner 3000 K Street NW Suite 500 Washington, DC 20007-5109			NAVARRO, ALBERT MARK	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/523,647

Applicant(s)

MURDIN ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8,9,11,40-42,44-46 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9,11,40-42,44-46 and 48-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants amendment filed February 23, 2004 has been received and entered. Claims 39, 43 and 47 have been canceled, and new claims 48-52 have been added. Accordingly, claims 8-9, 11, 40-42, 44-46, and 48-52 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 8-9, 11 and 39-47 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising a vector which encodes SEQ ID NO: 2, does not reasonably provide enablement for a vaccine vector comprising at least 12 consecutive amino acids is withdrawn in view of Applicants amendment.
2. The rejection of claims 8-9, 11 and 39-47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicants amendment.
3. The rejection of claim 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of said claim.

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 8-9, 11 and 39-47 under 35 U.S.C. 102(e) as being anticipated by Griffais et al is withdrawn in view of Applicants Declaration Pursuant to 37 CFR 1.131.

The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 8-9, 11, 40-42, 44-46, and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson et al in view of Denney Jr., and Scaria et al.

The claims are drawn to a vaccine vector comprising an isolated nucleic acid molecule which encodes SEQ ID NO: 2, wherein the nucleic acid molecule is operably linked to a promoter functional in a mammalian cell.

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Watson et al (Nucleic Acids Research Vol. 18, No. 17, page 5299, 1990) teach of the nucleotide sequence of the 60 kDa cysteine rich outer membrane protein of *Chlamydia pneumoniae*. The DNA sequence and encoded protein disclosed by Watson et al are identical to SEQ ID NO: 1-2 of the instant invention.

Watson et al do not teach of the nucleic acid molecule operably linked to a promoter functional in a mammalian cell.

Denney Jr. (US Patent Number 5,776,746) teach that the human cytomegalovirus (CMV) major immediate early gene enhancer/promoter is active in a broad range of cell types. Denney Jr. further teach that vectors containing the CMV enhancer/promoter increase the level of transcription of the desired antigen. (See column 16).

Scaria et al (US Patent Number 6,020,191) teach that vectors comprising a CMV promoter are advantageous in that they provide longer duration of expression of a transgene. (See column 4).

Given that 1) Watson et al has disclosed of the exact nucleotide sequence and exact encoded protein sequence as instantly claimed, and that 2) Denney Jr. has taught that the CMV promoter increases the level of transcription of a desired antigen, and that 3) Scaria et al has taught that CMV promoters are advantageous in that they provide longer duration of expression of a transgene, it would have been prima facie obvious to have taken the DNA molecule disclosed by Watson et al and to have fused it in frame to a CMV promoter. One of skill in the art would have been motivated to create this combination based on the teachings of Denney Jr. and Scaria et al that CMV promoters

increase the level of transcription of a desired antigen and provide longer duration of expression of a transgene.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Mark Navarro  
Primary Examiner  
May 10, 2004